

Department of Pesticide Regulation



California Notice 2006-06 Revision August 10, 2006

TO: PESTICIDE REGISTRANTS AND DATA SUBMITTERS

SUBJECT: FORMATTING REQUIREMENTS FOR SCIENTIFIC DATA SUBMITTED TO

THE DEPARTMENT OF PESTICIDE REGULATION

All scientific data submitted to the Department of Pesticide Regulation (DPR), <u>must</u> be formatted as described below. In the past, Pesticide Registration Branch (PRB) staff have, at times, assisted registrants by reformatting incorrectly formatted data. However, given the quantity of incorrectly formatted data being submitted, PRB no longer has the staff time or resources to fix incorrectly formatted data.

Effective immediately, upon receipt of an incorrectly formatted data submission, PRB will contact the data submitter and inform them that the data will be **shredded**. DPR will follow-up with a letter notifying the applicant that, with the exception of the data, which were shredded, DPR will maintain the remainder of the submission for nine months. If the applicant resubmits the data, properly bound, DPR will again begin processing the submission. If data submitted to support an application for registration or amendment is not resubmitted within six months, an additional application fee of \$750 is required.

ACCEPTABLE BINDERS:

- Use "ACCO-PRESS" or equivalent (e.g., SMEAD) pressboard folders (<u>not</u> plastic or vinyl) with holes punched in the left-hand 11-inch side of the pages. Folder prongs must open to the <u>front</u> of the volume. Do not put tape on prongs.
- If a study exceeds 400 pages, divide it into an appropriate number of ACCO-PRESS or equivalent folders. Leave at least one-half inch of length on each ACCO-PRESS folder prong for the addition of internal DPR documents.
- If a single study is placed in several volumes, clearly identify each volume in order (i.e. 1 of 5, 2 of 5, etc.).
- If the data that you are submitting contains fewer than 15 pages, you may use "Duo-Tang" type folders, with three prongs. Folder prongs must open to the **front** of the volume.
- Multiple small studies of similar type (e.g., several efficacy studies, all acute toxicity studies) may be bound together in one volume, provided divider pages and tabs are placed between each study. Include a table of contents and bind to a maximum thickness of 400 pages.

1001 | Street • P.O. Box 4015 • Sacramento, California 95812-4015 • www.cdpr.ca.gov



DO NOT USE:

ACCO folders with plastic spines/bindings Any plastic, vinyl, construction paper, or plain paper covers. 2-, 3-, 4-ring binders Folders with comb-type, "velo"-type, or spiral-type bindings.

FORMAT SPECIFICATIONS:

- Submit only **one** complete copy of each study.
- Only one **type** of study per binder (except as described above).
- Use <u>only</u> 81/2 by 11-inch white paper, printed with black ink, high contrast and good resolution.
- Ensure that **all** pages are present, numbered and in order.
- **<u>Do not</u>** include oversized computer printout or fold-out pages.
- **Bind** a copy of your cover letter in the front of **each** volume of the submission.
- <u>**Do not**</u> bind applications for registration, labels, or proof of federal registration in data Volumes
- If the original report is not in English, provide a complete English translation.
- Identify each study by the U.S. Environmental Protection Agency (U.S. EPA) guideline reference number and Master Record Identification Number (MRID).
- For any studies conducted on chemicals other than pesticide active ingredients or product formulations (e.g., inert ingredients, precursors, impurities, degradation products, etc.) you <u>must</u> clearly identify the type of study (e.g., acute oral LD50), the compound on which the study was conducted, and the reason for its inclusion in this submission (e.g., to support registration of product XYZ, EPA Reg. No. 123-456).
- If your submission is in response to a data call-in, reevaluation, risk assessment, or is an adverse effects disclosure, label it prominently, identifying the specific reason for the submission. **Do not** include any data in the submission that does not relate to the specific purpose of the submission.

ORDER OF STUDY VOLUME CONTENTS:

Front cover

Copy of cover letter to PRB

Title page

Abstract (no confidential information)

Introduction

Materials and Methods

Results and Discussion

Summary of Study

Data, tables, appendices

Analytical methods, etc.

U.S. EPA Data Evaluation Report (DER), if available

Back cover.

Please **do not** remove or move "confidential" information from where it occurs in a study.

STUDY VOLUME LABELING:

Please clearly label **each** volume with the following information:

- Name of data submitter
- Product brand name
- Type of data in the volume (e.g., chemistry, efficacy)
- Number of volumes in the entire submission (e.g., 1 of 27, 2 of 27, etc.).

If the submission is in response to a specific PRB request, be sure to include the reason for submission on the label (e.g., SB-950 data call-in).

If you have any questions regarding these guidelines, please e-mail Ms. Jacquelyn Rivers at *JRivers@cdpr.ca.gov*, or telephone her at (916) 324-3571.

Original signed by Barry Cortez	August 10, 2006
Barry Cortez, Chief	Date
Pesticide Registration Branch	
(916) 445-4377	

cc: Ms. Jacquelyn Rivers